

1419 5 JUN-3 P2:10

Ortho Molecular Products Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481
715.342.9881 Phone
800.332.2351
715.342.9866 Fax
orthomolecular products.com

Office of Special Nutritional (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

MAY 25 2004

Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Manufacturer: Ortho Molecular Products, Inc.

3017 Business Park Drive

P.O. Box 1060

Stevens Point, WI 54481

Statement Text: Gastrointestinal Support, Women's Health

Dietary Ingredients: Choline Bitartate, L-Methionine USP, Inositol, Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Lipotropic

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Melissa Slager

Document Control / Training Manager

Mussa Stager

Ortho Molecular Products



MAY 25 100

Ortho Molecular Products Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481
715.342.9881 Phone
800.332.2351
715.342.9866 Fax
orthomolecularproducts.com

Attachment of Lipotropic Labels

Suggested Use: As a dietary supplement, 5 capsules per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, yeast, artificial colors and flavors. If you are pregnant or nursing, consult your physician before taking this product.

As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. KEEP CONTAINER TIGHTLY CLOSED. STORE AT ROOM TEMPERATURE. KEEP OUT OF REACH OF CHILDREN.

Label ID L-OMP100-565150-B





Because Efficacy Matters*

Lipotropic

Dietary Supplement Product #565

150 Capsules

Supplement Facts Serving Size: 5 Capsules Servings Per Container: 30

5 capsules contain	Amount Per Serving	% Daily Value
Choline Bitartate	1,800 mg	*
L-Methronine USP	900 mg	*
Inositol	575 mg	*
* Of Daily Makes and a	ما ما ما ما	

* % Daily Value not established

Other Ingredients: Natural vegetable capsules. This product may contain one or more of the following: Ascorbyl Palmitate,
Magnesium Stearate, Microcrystalline Cellulose and Silicon
Dioxide. This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged. †These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure.

Mfg. by: Ortho Molecular Products, Inc. 3017 Business Park Drive. Stevens Point, WI 54481

OrthoMolecularProducts.com